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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,181	11/10/2000	Steven D. Jensen	7678.350.2	4245
22913	7590	07/18/2011	EXAMINER	
Workman Nydegger 1000 Eagle Gate Tower 60 East South Temple Salt Lake City, UT 84111			PRYOR, ALTON NATHANIEL	
			ART UNIT	PAPER NUMBER
			1616	
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			07/18/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/710,181	Applicant(s) JENSEN ET AL.
	Examiner ALTON PRYOR	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2011.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41,42,44-48,50-54,56-63,65-68,70-87 and 91-94 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 41,42,44-48,50-54,56-63,65-68,70-87,91-94 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 5/16/11 have been fully considered but they are not persuasive. Previous rejections and other issues not addressed below are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (USPN 5851512; 12/22/98), Fischer teaches a dental composition comprising a desensitizing agent such as 0.1 – 10% potassium nitrate (column 3 line 35- column 4 line 36, column 8 lines 51-67). Fischer teaches fluoride salts such as sodium fluoride (column 9 lines 1-17), peroxides such as carbamide peroxide and hydrogen peroxide (column 9 lines 36-47) and antimicrobial agents (tetracycline) can be added to the composition for anticariogenic activity, bleaching effect, and antimicrobial activity, respectively (column 4 lines 38-51). Example 8 used 10% urea peroxide (column 8 line 62 – column 15 line 12). Glycerine, propylene glycol and carboxypolymethylene (tackifying agents) can be added so that the composition adheres to teeth (column 8 lines 1-22). Water may also be added to the composition in a range of 0-50% by weight of the dental composition. (column 8 lines 11-22). Fischer teaches that EDTA or citric acid can be added to the dental composition in order to preserve stability of the dental composition (column 9 lines 28-35. Fischer

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teaches a method of treating teeth with the dental composition (column 11 line 54 - column 12 line 7). Fischer teaches a method of applying the dental composition to teeth by using a dental tray. The tray can be left on teeth for 15 minutes, one hour, or for any desire time period (column 11 line 54 - column 12 line 7). The method does not require brushing for the dental composition to work (column 5 lines 44-57). Fischer differs from the instant invention in that Fischer does not explicitly teach an invention to a non-abrasive composition or a dental composition that is substantially abrasive free. However, Fischer does not teach anywhere in the specification that his invention comprises an abrasive. Therefore, it is obvious that Fischer's invention is non-abrasive or substantially abrasive free.

Response to Applicants' Argument

Applicants argue that because 0.5% potassium nitrate unexpectedly yielded reduced oral sensitivity compared to when either 3% or 0% is used, it is within reason to conclude that amounts of potassium nitrate within narrowly tailored ranges on either side of 0.5% would yield greater desensitization compared to 3% or 0% potassium nitrate. Applicants argue that the nonobvious of a broader claimed range can be supported by unexpected data obtained from the testing of a narrower range. There is no case law that requires Applicants to only claim the specific species employed in the comparative study. The Examiner agrees with the Applicants. However, Applicants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce

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and make claim to a concentration trend for potassium nitrate and carbamide peroxide.

The examples are not commensurate in scope with the claims, including claims 61 and 94.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12,15,16 of U.S. Patent No. 5851512. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent. USPN '512 does not require an abrasive. Fischer differs from the instant invention in that Fischer does not claim an invention to a non-abrasive composition or a dental composition that is substantially abrasive free as claimed. However, Fischer does not teach anywhere in the specification that his

invention comprises an abrasive. Therefore, it is obvious that Fischer's invention is non-abrasive or substantially abrasive free. Fischer differs from the instant invention in that Fischer does not make claim to an invention comprising 10-30% peroxide and 0.01% to 2% potassium nitrate. However, Fischer does suggest such an invention.

Response to Applicants' Argument

Applicants argue that USPN '512 claims do not recite specific ranges of 0.01 to less than 2% potassium nitrate, particularly 0.5% concentration for which the testing shows unexpected results. The Examiner argues that '512 recites potassium nitrate concentration in claim 4 of "about 0.1 to about 10%" and in claim 5 "about 1 to about 7%". The ranges recited in the claims of '512 encompasses the instantly claimed range of 0.01 to less than 2% as well as 0.5% potassium nitrate, making the instantly claimed ranges obvious. The Examiner argues that Applicants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce and make claim to a concentration trend for potassium nitrate and carbamide peroxide. The examples are not commensurate in scope with the claims, including claims 61 and 94.

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7,10-20 of U.S. Patent No. 6368576. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant application and patent discloses a method of applying a composition comprising a

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desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent to teeth with the aid of a tray. Jensen et al. differ from the instant invention in that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01% to 2% potassium nitrate. However, Jensen et al. do suggest such invention.

Response to Applicants' Argument

Applicants argue that USPN '576 claims do not recite specific ranges of 0.01 to less than 2% potassium nitrate, particularly 0.5% concentration for which the testing shows unexpected results. The Examiner argues that '576 recites potassium nitrate concentration in claim 10 of "up to about 10%". The range recited in the claim 2 of '576 encompasses the instantly claimed range of 0.01 to less than 2% as well as 0.5% potassium nitrate, making the instantly claimed ranges obvious. The Examiner argues Applicants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce and make claim to a concentration trend for potassium nitrate and carbamide peroxide. The examples are not commensurate in scope with the claims, including claims 61 and 94.

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8,10,11,13-19,23-26 of U.S. Patent No. 6309625. Although the conflicting claims are not identical, they are not patentably distinct from each other because both

instant application and patent discloses a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent. USPN '625 does not require an abrasive. Jensen et al. differ from the instant invention in that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01% to 2% potassium nitrate. However, Jensen et al. do suggest such invention.

Response to Applicants' Argument

Applicants argue that USPN '625 claims do not recite specific ranges of 0.01 to less than 2% potassium nitrate, particularly 0.5% concentration for which the testing shows unexpected results. The Examiner argues that '625 recites potassium nitrate concentration in claim 2 of "about 0.1 to about 50%". The range recited in the claim 2 of '625 encompasses the instantly claimed range of 0.01 to less than 2% as well as 0.5% potassium nitrate, making the instantly claimed ranges obvious. The Examiner argues Applicants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce and make claim to a concentration trend for potassium nitrate and carbamide peroxide. The examples are not commensurate in scope with the claims, including claims 61 and 94.

Claims 41,42,44-48,50-54,56-63,65-68,70-87,91-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6306370. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because both instant application and patent discloses a method of applying a composition comprising a desensitizing agent (potassium nitrate, citric acid), a tackifying agent (carboxypolymethylene), cetyl pyridinium bromide, and a bleaching agent to teeth with the aid of a tray. Jensen et al. differ from the instant invention in that Jensen et al. do not make claim to an invention comprising 10-30% peroxide and 0.01% to 2% potassium nitrate. However, Jensen et al. do suggest such invention.

Response to Applicants' Argument

Applicants argue that USPN '370 claims do not recite specific ranges of 0.01 to less than 2% potassium nitrate, particularly 0.5% concentration for which the testing shows unexpected results. The Examiner argues that '370 recites potassium nitrate concentration in claim 1 of "at least about 0.1%", in claim 2 "at least about 1 to about 7%" and in claims 14 and 16 "about 0.1 to about 10%". The ranges recited in the claims of '370 encompasses the instantly claimed range of 0.01 to less than 2% as well as 0.5% potassium nitrate, making the instantly claimed ranges obvious. The Examiner argues that Applicants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide. The Examiner argues that the testing of a single data point is not enough data to deduce and make claim to a concentration trend for potassium nitrate and carbamide peroxide. The examples are not commensurate in scope with the claims, including claims 61 and 94.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTON N. PRYOR whose telephone number is (571)272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/

Primary Examiner, Art Unit 1616